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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,054	03/27/2000	NEAL ROSEN	696-US	9414

7590

01/23/2003

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EXAMINER

GOLDBERG, JEROME D

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/445,054

Applicant(s)

ROSEN ET AL.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12,30 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) 12,30 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-45, 47 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17 (e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 3, 2002 has been entered.

Claims 12, 30 and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Applicants elected the synergistic combination of 1-(3-chlorophenyl)-4-[1-(4-cyanobenzyl)-5-imidazolylmethyl]-2-piperazinone and paclitaxel with traverse in Paper No. 7. The instant claims 40-45, 47 and 48 are directed to many synergistic combinations (note claim 44 directed to 210 prenyl-protein transferase inhibitors). Further, the prenyl-protein transferase inhibitor is directed to all types of heterocyclic as well as non-heterocyclic compounds, which would be classified in many different places in class 514. Therefore, the restriction requirement is deemed proper and is Final.

Cancellation of the non-elected synergistic combinations from the instant claims is now required.

Claims 40-45, 47 and 48 are being examined as they read on the elected synergistic combination as set forth above.

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Claims 40-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "and neurological tumor" in claim 40-45 should recite " or neurological tumor". The term "and" in claim 44, page 15 of Paper No. 17, line 21 should be deleted. The term "and desoxyepothilone B" in claim 43, line 3 should recite "or desoxyepothilone B".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Anthony et al. patent of record taken with the Slichenmyer et al. reference.

The Anthony et al. patent has a effective filing date of March 1, 1996 while the instant application has an effective date of January 21, 1998. The Anthony et al. patent teaches, "the instant compounds may be useful in combination with known anti-cancer and cytotoxic agents" (col. 54, lines 36-38). The patent further states that the "present invention also encompasses a pharmaceutical composition useful in the treatment of cancer..." (col. 54, lines 50 and 51). The patent teaches applicants' elected 1-(3-Chlorophenyl)-4-[1-(4-cyanobenzyl)-5-imidazolylemethyl]-2-piperazinme (col. 19, lines 48 and 49). The Slichenmyer et al. reference, having an effective date of 1991 teaches taxol (paclitaxel for treating cancers in clinical trials. The reference and patent do not teach the specific ingredients together. However, one skilled in this art would find ample motivation from the prior art supra to combine the well known anti-cancer agents together where the results obtained thereby are no more than the additive effects of the ingredients. See *In re Sussman*, 1943 C.D. 518. Claims directed to a showing of greater than the additive effect would overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/LR  
January 21, 2003



JEROME D. GOLDBERG  
PRIMARY EXAMINER